

## REMARKS

Claims 37-44 and 77-84 were allowed in the Office Action.

Claims 45 and 55 have been amended.

### 35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (emphasis added).

#### Claims 45-49

Claim 45 has been amended to positively claim the anastomosis device, and to clarify the mechanical relationship between the tubes and the anastomosis device. Amended claim 45 claims “[a]n anastomosis system, comprising: a one-piece anastomosis device; a first tube connected to said anastomosis device; and a second tube concentric with said first tube, wherein at least one of said first and second tubes is rotatable with respect to the other said tube to apply torque to said anastomosis device about its longitudinal axis.”

In contrast, U.S. Pat. No. 5,234,447 to Kaster et. al. (“Kaster”) instead discloses sliding a sleeve 13 “forwardly” to “cause the anvil disposed on its forward end to contact the plurality of exterior wall engagement member (44) and thereby urge them forward into a piercing and engaging orientation.” (column 7, lines 2-7; Figure 19). Kaster nowhere discloses a first tube and a second tube wherein “at least one of said first and second tubes is rotatable with respect to the other said tube.” (emphasis added). Kaster additionally fails to disclose an anastomosis tool “wherein rotation of at least one of said first and second tubes applies torque to said anastomosis device about its longitudinal axis.” Not only does Kaster

fail to disclose rotation of one or more tubes, but also Kaster fails to describe applying “torque to said anastomosis device about its longitudinal axis” as a result of such rotation. Instead, in Kaster, the bending of each member 44 as a result of the linear motion of the sleeve 13 is about an axis perpendicular to the longitudinal axis of the anastomosis device.

Thus, Kaster neither expressly nor inherently discloses each and every element claimed in amended claim 45, and it is believed that claim 45 is in condition for allowance. Claims 46-49 depend directly or indirectly from claim 45, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

#### Claims 55-58

Amended claim 55 claims “[a]n anastomosis tool for use in connecting an end of a graft vessel to the side of a target vessel, the tool comprising a vessel penetrating member configured to penetrate the target vessel, wherein said vessel penetrating member is located outside the lumen of the graft vessel at all times, and wherein the tool is configured to penetrate the target vessel and deliver a one-piece anastomosis device to connect the graft vessel to the target vessel.”

In contrast, U.S. Pat. No. 6,391,036 to Berg et. al. (“Berg”) nowhere discloses a “vessel penetrating member...located outside the lumen of the graft vessel at all times.” Berg discloses a head 102 that may “act as an incisor or dilator,” where that head 102 is located at the distal “end of structure 100.” (column 10, lines 1-16; Figure 25). The structure 100 is “an elongated tube or rod which extends axially through the connector” as well as through the lumen of the graft conduit 30. (column 9, line 67 through column 11, line 1; column 9, lines 27-29; Figure 25). The graft conduit 30 is tubular, and as a result the only way to withdraw the structure 100 and the attached head 102 from the lumen of the graft conduit 30 without tearing or destroying the graft conduit 30 is proximally through the lumen of the graft conduit

30. If the head 102 were advanced away from the user, the head 102 would remain in the target vessel 50 of the patient and the structure 100 would remain in the lumen of the graft conduit 30, and the head 102 would potentially penetrate the opposite wall of the target vessel 50. (e.g., Figure 15). Such penetration would be undesirable at best. Thus, the head 102 of Berg is necessarily configured for proximal withdrawal inside the lumen of the graft conduit 30, rather than outside the lumen of the graft conduit 30, and consequently the head 102 of Berg is not "located outside the lumen of the graft vessel at all times."

Thus, Berg neither discloses nor suggests a "vessel penetrating member...located outside the lumen of the graft vessel at all times" as claimed in amended claim 55, and it is believed that claim 55 is in condition for allowance. Claims 56-58 depend directly or indirectly from claim 55, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

#### **REQUEST FOR ALLOWANCE**

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



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